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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,378	11/19/2003	Aquilur Rahman	224491	6704

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LEYDIG VOIT & MAYER, LTD  
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EXAMINER

RUSSEL, JEFFREY E

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/717,378

Applicant(s)

RAHMAN ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-9,11-21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9,11-21 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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1. Claims 1-3, 5-9, 11-21, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “conventional irinotecan”, which occurs at claim 1, line 6, and claim 11, line 5, is indefinite. It is not clear what constitutes “conventional” irinotecan, as opposed to unconventional irinotecan. The term is not defined in the specification or in the prior art. The specification describes prior art uses of irinotecan hydrochloride at page 1, lines 25-34, but does not describe what components are present in the composition and does not describe how the compositions are administered. Multiple irinotecan compositions are taught in the prior art literature. See, e.g., the Sadzuka et al article (Current Drug Metabolism, Vol. 1, pages 31-48), in which irinotecan hydrochloride is entrapped in liposomes comprised of one of two lipids and optionally modified by PEG. The Sadzuka et al article (Cancer Letters, Vol. 127, pages 99-106) teaches the same liposomal compositions as above, and in addition teaches an irinotecan solution. The Okuno et al article (Cancer Research, Vol. 60, pages 2988-2995) teaches irinotecan in the form of a conjugate with carboxymethyl dextran via a triglycine spacer. Bouscarel et al (U.S. Patent No. 6,407,117 at column 15, line 64 - column 16, line 67 and claim 4), and Ratain et al (U.S. Patent No. 5,786,344 at column 58, line 30 - column 60, line 67) teach numerous different irinotecan compositions and methods of administration. It is not possible to determine whether or not any of these prior art compositions are the “conventional irinotecan” contemplated by Applicants. In the absence of an understanding of what constitutes “conventional irinotecan”, it will not be possible to determine whether a particular liposomal entrapped irinotecan composition meets the functional requirement set forth in the claims, i.e. whether or not it demonstrates an irinotecan plasma concentration 200-fold higher than

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conventional irinotecan. One of ordinary skill in the art cannot ascertain the metes and bounds of the claimed invention.

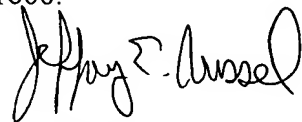
2. Claims 1-3, 5-9, 11-21, and 23 are objected to because of the following informalities: At claim 1, line 5, and claim 11, line 4, "a" should be changed to "an". Appropriate correction is required.

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The limitations in claims 1 and 11 that the liposomal entrapped irinotecan demonstrates a plasma concentration 200-fold higher than conventional irinotecan is not recited in the specification. The subject matter recited in claims 3 and 5 is also not recited anywhere in the specification.

4. The rejections set forth in the previous Office action are withdrawn in view of the amendments to the claims and for the reasons set forth in Applicants' response.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel  
Primary Patent Examiner  
Art Unit 1654

JRussel  
July 6, 2005